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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,132	08/06/2001	Gary S. Saylor	6704-15-1	8944
43463	7590	08/22/2005	EXAMINER	
RUDEN, MCCLOSKEY, SMITH, SCHUSTER & RUSSELL, P.A. 222 LAKEVIEW AVE SUITE 800 WEST PALM BEACH, FL 33401-6112			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Interview Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/923,132		SAYLER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	David A. Lambertson		1636	

All participants (applicant, applicant's representative, PTO personnel):

(1) David A. Lambertson.

(3) Amy Ostrum.

(2) Stanley Kim.

(4) \_\_\_\_\_.

Date of Interview: 14 July 2005.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: All claims.

Identification of prior art discussed: Lyngberg et al., Bansemir et al., Simpson et al..

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
JAMES KETTER  
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's representative requested an interview to discuss the rejections under 35 USC § 112, first paragraph and 35 USC § 103.

Rejections under 35 USC 112, first paragraph- Applicant inquired as to how many examples of response elements would be sufficient to establish the representative number of examples necessary to satisfy the Written Description requirement. The Office first indicated that a number of claims were not even limited to detecting analytes by using a "response element," but were in fact much broader in scope; this was also indicated in the previous Office Actions. Secondly, it was indicated that the number of examples necessary to show possession of a genus changes based on the breadth of the scope of that genus. In the instant case, the claims are drawn to detecting any compound, due to breadth in scope of the term "analyte." Because there are literally billions of "analytes," a very large number of examples would be required to show the skilled artisan that the inventor could detecting any compound that exists. Furthermore, it was indicated that 35 specific examples represented a very small percentage of analytes that could be detected given the large number (billions) of analytes that exist, and that this could not be considered a representative sample. Additionally, each of those elements was structurally distinct from each other (having different nucleic acid sequences), and required different factors to recognize these sequences to drive the expression of a reporter gene, making them significantly different in structure-function terms. Finally, it was again noted that the previous Office Action indicated specific analytes that have no known response elements, establishing that the genus of analytes that must be detected within the broad scope of the claims could not be detected by the claimed invention.

Rejections under 35 USC § 103- Applicant first discussed their interpretation that the plasmids in Lyngberg could not be considered "stably expressed." The Office indicated that the term "stably expressed" is a relative term that is not defined in the specification, thus anything can reasonably be considered "stably expressed" under certain contexts and absent evidence in the specification excluding those contexts as being "stably expressed." Furthermore, Applicant was directed to the teachings of Simpson, also used in combination with Lyngberg in rejections under 35 USC § 103, that showed the interchangeability of plasmid expression and expression following an integration event. Applicant then addressed the lack of a teaching that the reporter gene used in any of the references could be detected by the unassisted eye. The Office responded by saying that the reporter gene used in Lyngberg was identical to the reporter used in the instant invention, and that if it could not be detected by the unassisted eye in Lyngberg, then it could not be detected by the unassisted eye in the instant invention. It was then discussed that detection by the unassisted eye was relative to the expression level from the response element, which was in turn dependent on the presence of an analyte (such as mercury); thus, detection by the unassisted eye would actually be dependent on the amount of analyte present in a sample. Therefore, the reporter gene used by Lyngberg can be detected by the unassisted eye in the same manner that the instant reporter could be detected, there being no difference between the reporters that are used. Finally, Applicant suggested that there was no motivation to combine any of the teachings because Lyngberg does not report any problems with their assay or device that would require improvement. The Office indicated that Lyngberg does not indicate that their assay or device is perfect and requires no improvement, and that a suitable motivation statement for combining the references (a simplified detection unit and method, as taught by Banesmir) was provided in the previous Office Actions, to which no argument has been provided.